



October 16, 2003

Join ASA!

Members Only

Search

Home &gt; Newsletters &gt; December 2002 &gt; News

## ASA NEWSLETTER

Index

December 2002  
Volume 66

Number 12

## FEATURES

## Governmental Affairs

- Today's ASA: Making A Difference in Governmental Affairs
- Facing a Brave New World of Political Involvement
- Alabama: 2002 Star of ASAPAC
- ASAPAC in 2002: How and Who Your Contributions Helped
- Revisiting Medicare Fees for Resident Supervision
- WEDI, HIPAA and U

## ARTICLES

- ASA Web Site: Transformed
- 2002 Annual Meeting: Swamped in Orlando!
- Hepatitis C Outbreak: More Than 50 Infected by Reused Needles and Syringes
- Fighting Pain With Knowledge
- FDA Alert: Update on Droperidol and the FDA
- Keeping a Finger on the Pulse of Transfusion Practices
- 2003 PBLD Program—Open Call for Case Submissions
- Updated 'Sedation' Videotape Now Available
- ABA Announces

## Update on Droperidol and the FDA

Nancy Chang, M.D.  
Bob Rappaport, M.D.

In December 2001, the Food and Drug Administration (FDA) placed a "black box" warning on droperidol labels because of serious concerns about its potential to cause life-threatening ventricular dysrhythmias. Droperidol has been shown to cause QTc prolongation, and in March 2001, worldwide marketing of droperidol outside the United States was discontinued following a risk-benefit analysis and examination of reported cases of QTc prolongation.

These events led the FDA to review its own postmarketing safety database, Janssen's analysis and the available literature on droperidol and QTc prolongation. Dose-dependent QTc prolongation and association with torsades de pointes (TdP) upon challenge and rechallenge with droperidol was well documented in the literature. In addition, the postmarketing safety database was found to contain cases of QTc prolongation, TdP, cardiac arrest and death associated with doses of droperidol at and below the lowest labeled dose of 2.5 mg.

Anesthesiologists typically use very low doses of droperidol for the treatment and prevention of nausea and vomiting — well below the lowest labeled dose of 2.5 mg. — and the potential for QTc prolongation at these low doses has not been well characterized. In order for the FDA to approve droperidol at doses below 2.5 mg, the Administration must be provided with data that satisfy regulatory requirements for the demonstration of efficacy and safety at these doses.

Droperidol has been a priority within the FDA as evidenced by its willingness to devote significant human and financial resources to continue the evaluation of the pharmacology and safety profile of this drug. A comprehensive evaluation of the postmarketing safety databases of droperidol and its alternatives has been undertaken, and the FDA sponsored a study recently that measured QTc prolongation after administration of droperidol to healthy volunteers.

The study utilized a crossover design with droperidol doses of 0 mg, 0.625 mg, 2.5 mg and 5 mg. Although the study was prematurely terminated because of significant neuropsychiatric

About ASA

Patient Education

Clinical Information

Continuing Education Resources

Annual Meeting

Calendar for Meetings

Office of Governmental &amp; Legal Affairs

Practice Management

Resident and Career Information

Placement Service

Publications and Services

Related Organizations

News Archives

Links of Interest

adverse effects, including dysphoria and anxiety, there were several findings of note. Impressive QTc prolongations (approximately 80 ms from baseline) were found in individuals following the 2.5 mg and the 5 mg doses, even though only seven and three subjects, respectively, received these doses. Compared to placebo, the 0.625 mg dose did not appear to have a significant effect on QTc; however, this cannot be considered a definitive finding as only five individuals were studied at this dose. Additional investigation will be required to further define the relationship between QTc prolongation, potential for dysrhythmia and various doses of droperidol.

The FDA is now exploring options to obtain data that satisfy regulatory standards for the demonstration of safety and efficacy at doses lower than 2.5 mg. An advisory committee meeting to discuss droperidol also is planned. We continue to closely follow the adverse events database for droperidol, and we urge practitioners to participate in the postmarketing safety assessment process by reporting all potential drug-related adverse events. For more information on reporting adverse events, visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

*Nancy Chang, M.D., is Medical Team Leader for Anesthesia and Critical Care, Division of Anesthesia, Critical Care and Addiction Drug Products, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, Maryland.*

*Bob Rappaport, M.D., is Acting Division Director, Division of Anesthesia, Critical Care and Addiction Drug Products, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, Maryland.*

- Information for Authors

## DEPARTMENTS

- Ventilations
- Administrative Update
- Washington Report
- Practice Management
- State Beat
- Residents' Review
- What's New In...
- ASA News
- In Memoriam
- Letters to the Editor
- FAER Report

The views expressed herein are those of the authors and do not necessarily represent or reflect the views, policies or actions of the American Society of Anesthesiologists.

→ NL Archives

→ Information for Authors



return to top